

**Board of Pharmacy
Amendments to Title 16, Division 17 of the
California Code of Regulations**

Article 9 --Citations and Fines

Amend Section 1775

§1775. Issuing Citations and Fines.

~~(a) A committee of the board~~ The executive officer or his/her designee may issue a citation ~~which may contain either or both an administrative fine and an order of abatement~~ containing orders of abatement and fines for:

- (1) A violation of the Pharmacy Law (Business and Professions Code 4000 et seq.).
- (2) A violation of a regulation adopted by the board.
- (3) A violation of the Confidentiality of Medical Information Act (Civil Code 56 et seq.).
- (4) Defaulting on a United States Department of Health and Human Services education loan.
- (5) A violation of other statutes or regulations for which the board may issue a citation.

~~any violation of the Pharmacy Law or regulations adopted pursuant thereto. For the purposes of this article, "committee of the board" means a committee of board members appointed by the board president to consider investigations of alleged violations.~~

(b) Each citation shall be in writing and shall describe with particularity the nature and facts of the violation, including a reference to the statute or regulations alleged to have been violated. The citation shall be served upon the individual personally or by certified mail.

(c) A citation must inform the cited person or entity that if he/she or it desires a hearing to contest the finding of a violation, that hearing shall be requested by written notice to the board within 30 days of the issuance of the citation. If a hearing is not requested pursuant to this article, payment of any fine shall not constitute an admission of the violation charged.

~~(d) A committee of the board shall meet periodically in both the northern and southern portions of the state for the purpose of reviewing alleged violations, including notices of violation issued by the board inspectors, and issuing citations to licensees of the board. A person or entity shall appear, upon request of the board, before a committee of the board. The request to appear shall include a summary of alleged violations to be reviewed at that hearing. Persons or entities may reschedule their appearance before a committee of the board to review an alleged violation once. A committee of the board may issue a citation and impose a fine, and/or an order of abatement in the absence of a person or entity who fails to appear a second time. Citations shall be issued within 60 days of the committee meeting where the determination to issue the citation was made.~~

Authority cited: Sections 125.9, 148, 685 and 4005, Business and Professions Code, Section 56.36 of the Civil Code. Reference: Sections 125.9, 148, and 685 ~~and 148~~, Business and Professions Code, Section 56.36 of the Civil Code.

Add Section 1775.1

§1775.1. Amount of Fines

(a) The fine for violating the Pharmacy Law or regulations adopted pursuant thereto shall not exceed the amount specified in Section 125.9 of the Business and Professions Code, except for a fine issued pursuant to Section 4067 or Section 4127.4 of the Business and Professions Code.

(b) The fine for violating the Confidentiality of Medical Information Act shall not exceed the amount specified in Section 56.36 of the Civil Code.

(c) The fine for defaulting on a United States Department of Health and Human Services education loan shall not exceed \$2,500.

(d) Failure of a person or entity cited to pay a fine within 30 days of the date of assessment, unless the citation is being appealed, may result in disciplinary action by the board. When a citation is not contested and a fine is not paid, the full amount of the fine shall be added to the fee for renewal of the license and the license shall not be renewed without payment of the renewal fee and fine.

Authority cited: Sections 125.9, 148, 685 and 4005, Business and Professions Code, Section 56.36 of the Civil Code. Reference: Sections 125.9, 148, 685, 4067 and 4127.4 Business and Professions Code, Section 56.36 of the Civil Code.

Repeal Section 1775.15.

§1775.15. Executive Officer, Citations.

~~(a) The executive officer may issue citations for violations of the following:~~

- ~~(1) Article 8 of the Pharmacy Law (Commencing with Business and Professions Code Section 4130) and any regulations relating to medical device retailers.~~
- ~~(2) Article 9 of the Pharmacy Law (Commencing with Business and Professions Code Section 4140) and any regulations relating to hypodermic needles and syringes.~~
- ~~(3) Article 11 of the Pharmacy Law (Commencing with Business and Professions Code Section 4160) and any regulations relating to wholesalers and manufacturers.~~
- ~~(4) Article 13 of the Pharmacy Law (Commencing with Business and Professions Code Section 4180) and any regulations relating to nonprofit or free clinics.~~
- ~~(5) Article 14 of the Pharmacy Law (Commencing with Business and Professions Code Section 4190) and any regulations relating to surgical clinics.~~
- ~~(6) Article 15 of the Pharmacy Law (Commencing with Business and Professions Code Section 4196) and any regulations relating to veterinary food animal drug retailers.~~
- ~~(7) Article 17 of the Pharmacy Law (Commencing with Business and Professions Code Section 4230) and any regulations relating to continuing education.~~
- ~~(8) Section 1708.2 of Title 16 of the California Code of Regulations.~~

~~(b) The executive officer may also issue citations, in accordance with Section 148 of the Business and Professions Code, against any person (as defined in Section 302 of the Code) who is performing or who has performed services for which licensure is required under the Pharmacy Law or regulations adopted pursuant thereto. Each citation issued under this section shall contain an order of abatement. The sanction authorized under this section shall be separate from and in addition to any other civil or criminal remedies.~~

~~(c) In addition to the formal appeals process contained in Business and Professions Code Section 125.9(b)(4) and Section 1775.4(a) of Title 16 of the California Code of Regulations, an intermediate appeal of any citation issued by the executive officer shall be heard by a committee of the board where the appellant appears in person before the committee. Requests for a hearing by a committee of the board must be submitted within 14 days of receipt of the citation. A committee of the board may either affirm, modify (but not increase) or dismiss the citation, including any administrative fine or order of abatement.~~

Authority cited: Sections 125.9, 148 and 4005, Business and Professions Code. Reference: Sections 125.9 and 148, Business and Professions Code.

Amend Section 1775.2.

§1775.2. Amount of Fines and Factors Considered.

~~In no event shall a fine issued pursuant to Section 1775 exceed \$2,500.~~

~~In his/her or its discretion, the executive officer or a committee of the board may issue a citation with an order of abatement without levying a fine.~~

In assessing the amount of an administrative fine, except violations of the Confidentiality of Medical Information Act and when assessing a fine pursuant to Business and Professions Code section 685, the executive officer or a committee of the board shall give due consideration to the following factors shall be considered:

- (a) The gravity of the violation.
- (b) The good or bad faith of the cited person or entity.
- (c) The history of previous violations.
- (d) Evidence that the violation was or was not willful.
- (e) The extent to which the cited person or entity has cooperated with the board's investigation.
- (f) The extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violation.
- (g) Other matters as may be appropriate.
- (h) The number of violations found in the investigation.

Authority cited: Sections 125.9, 148, 685, and 4005, Business and Professions Code, Section 56.36, Civil Code. Reference: Sections 125.9, and 148 and 685, Business and Professions Code, Section 56.36, Civil Code.

Amend Section 1775.3

§1775.3. Compliance with Orders of Abatement.

(a) If a cited person or entity who has been issued an order of abatement is unable to complete the correction within the time set forth in the citation because of conditions beyond his/her or its control after the exercise of reasonable diligence, the person or entity cited may request, from the board, an extension of time in which to complete the correction from the board. Such a request shall be in writing and shall be made within the time set forth for abatement.

(b) When an order of abatement is not contested or if the order is appealed and the person or entity cited does not prevail, failure to abate the violation charged within the time specified in the citation shall constitute a violation and failure to comply with the order of abatement. An order of abatement shall either be personally served or mailed by certified mail. The time allowed for the abatement of a violation shall begin when the order of abatement is final and has been served or received. Such failure Failure to comply with an order of abatement shall constitute a ground for revocation or suspension of the license, permit, or registration.

Failure of a person or entity cited to pay a fine within 30 days of the date of assessment, unless the citation is being appealed, may result in disciplinary action by the board. When a citation is not contested and a fine is not paid, the full amount of the fine shall be added to the fee for renewal of the license and the license shall not be renewed without payment of the renewal fee and fine.

Authority cited: Sections 125.9, 148, 4005, Business and Professions Code. Reference: Sections 125.9 and 148, Business and Professions Code.

§1775.4. Contested Citations.

(a) Any person or entity served with a citation may contest the citation by appealing to the board in writing within 30 days of the issuance of the citation. Appeals shall be conducted pursuant to the adjudication provisions of the Administrative Procedure Act (Government Code 11340 et seq.). Government Code Section 11500 et seq.

(b) In addition to requesting a hearing, as provided for in subdivision (a) subsection (b)(4) of Section 125.9 of the Business and Professions Code, the person or entity cited may, within 14 calendar days after service of a citation by the board inspector, submit a written request for an informal office conference. The time allowed for the request shall begin the first day after the citation has been received by the cited person or entity. The person or entity cited may contest any or all aspects of the citation. The informal office conference will be conducted by the executive officer or his/her designee within 30 calendars days of receiving the request, a supervising inspector or board member(s).

(c) The executive officer ~~or his/her designee, supervising inspector or board member(s)~~ shall hold an informal office conference upon request as provided for in subdivision (b) section 1775.4(b) with the person or entity cited ~~and/or his/her or its~~ and their legal counsel or authorized representative if they desire representation at the informal office conference. At the conclusion of the informal office conference, the executive officer ~~or his/her designee, supervising inspector or board member(s)~~ may affirm, modify or dismiss the citation, including any administrative fine levied or order of abatement issued. The executive officer ~~or his/her designee, supervising inspector or board member(s)~~ shall state in writing the reasons for their action and serve or send by certified mail, a copy of their findings and decision to the person or entity cited within 14 calendar days from the date of the office conference. This decision shall be deemed to be a final order with regard to the citation issued, including the administrative fine levied and/or an order of abatement.

(d) The person or entity cited does not waive their ~~his/her or its~~ request for a hearing to contest a citation by requesting an office conference after which the citation is affirmed by the executive officer ~~or his/her designee, supervising inspector or board member(s)~~. If the citation is dismissed after the office conference, the request for a hearing on the matter of the citation shall be deemed to be withdrawn. If the citation, including any administrative fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. If a hearing is requested for the subsequent citation, it shall be requested within 30 days of the issuance of the subsequent citation. ~~in accordance with subsection (b)(4) of Section 125.9 of the Business and Professions Code.~~

Authority cited: Sections 125.9, 148, 4005, Business and Professions Code. Reference: Sections 125.9 and 148, Business and Professions Code.

Article 9.6. Citation and Fine -- Patient Privacy Violations

Repeal Section 1777

§1777. Authority to Issue Citations.

~~(a) A committee of the board may issue citations against a licensee containing orders of abatement and fines for the disclosure of medical information in violation of the Confidentiality of Medical Information Act (Commencing with Section 56 of the Civil Code). Any citation issued for the willful disclosure of medical information for financial gain shall be accompanied by an order of abatement that requires the disgorgement of any proceeds or other consideration obtained as a result of the violation. For the purposes of this article, "committee of the board" means a committee of board members appointed by the board president to consider investigations of alleged violations.~~

~~(b) Each citation shall be in writing and shall describe with particularity the nature and facts of the violation, including a reference to the statute or regulations alleged to have been violated. The citation shall be served upon the licensee personally or by certified mail.~~

~~(c) A citation must inform the cited person or entity that if he/she or it desires a hearing to contest the finding of a violation, that hearing shall be requested by written notice to the board within 30 days of the issuance of the citation. Payment of any fine shall not constitute an admission of the violation charged.~~

~~(d) A committee of the board shall meet periodically in both the northern and southern portions of the state for the purpose of reviewing alleged violations, including notices of violation issued by the board inspectors, and issuing citations to licensees of the board. A licensee shall appear, upon request of the board, before a committee of the board. The request to appear shall include a summary of alleged violations to be reviewed at that meeting. Persons or entities may reschedule their appearance before a committee of the board to review an alleged violation once. A committee of the board may issue a citation and impose a fine, and/or an order of abatement in the absence of a person or entity who fails to appear a second time. Citations shall be issued within 60 days of the committee meeting where the determination to issue the citation was made.~~

Authority cited: Section 4005, Business and Professions Code; and Section 56.36, Civil Code. Reference: Section 56.36, Civil Code; and Section 4301, Business and Professions Code.

Repeal Section 1777.1

§1777.1. Amount of Fines for Violations by Pharmacists.

- ~~(a) Any pharmacist, who negligently discloses medical information in violation of the provisions the Confidentiality of Medical Information Act shall be subject, irrespective of the amount of damages suffered by the patient as a result of that violation, to an administrative fine not to exceed two thousand five hundred dollars (\$2,500) per violation.~~
- ~~(b) A pharmacist, who knowingly and willfully obtains, discloses, or uses medical information in violation of the Confidentiality of Medical Information Act shall be subject on a first violation, for an administrative fine not to exceed two thousand five hundred dollars (\$2,500) per violation, or on a second violation for an administrative fine not to exceed ten thousand dollars (\$10,000) per violation, or on a third and subsequent violation for an administrative fine not to exceed twenty five thousand dollars (\$25,000) per violation.~~
- ~~(c) A pharmacist, who knowingly and willfully obtains, discloses, or uses medical information in violation of the Confidentiality of Medical Information Act for financial gain shall be liable on a first violation, for an administrative fine not to exceed five thousand dollars (\$5,000) per violation, or on a second violation for an administrative fine not to exceed twenty five thousand dollars (\$25,000) per violation, or on a third and subsequent violation for an administrative fine not to exceed two hundred fifty thousand dollars (\$250,000) per violation.~~
- ~~(d) Nothing in this subdivision shall be construed as authorizing an administrative fine under both this section and section 1777.2 for the same violation.~~

Authority cited: Section 4005, Business and Professions Code; and Section 56.36, Civil Code. Reference: Section 56.36, Civil Code; and Section 4301, Business and Professions Code.

Repeal Section 1777.2

§1777.2. Amount of Fines for Violations by Non-Professional Licensees.

- ~~(a) Any person or entity licensed by the board, other than a pharmacist, that negligently discloses medical information in violation of the provisions the Confidentiality of Medical Information Act shall be subject, irrespective of the amount of damages suffered by the patient as a result of that violation, to an administrative fine not to exceed two thousand five hundred dollars (\$2,500) per violation.~~
- ~~(b) Any person or entity licensed by the board, other than a pharmacist, who knowingly and willfully obtains, discloses, or uses medical information in violation of the Confidentiality of Medical Information Act shall be subject to an administrative fine not to exceed twenty five thousand dollars (\$25,000) per violation.~~
- ~~(c) Any person or entity licensed by the board, other than a pharmacist, who knowingly or willfully obtains or uses medical information in violation of the Confidentiality of Medical Information Act for the purpose of financial gain shall be liable for an administrative fine not to exceed two hundred fifty thousand dollars (\$250,000) per violation.~~
- ~~(d) Nothing in this subdivision shall be construed as authorizing an administrative fine or civil penalty under both this section and section 1777.1 for the same violation.~~

Authority cited: Section 4005, Business and Professions Code; and Section 56.36, Civil Code. Reference: Section 56.36, Civil Code; and Section 4301, Business and Professions Code.

Repeal Section 1777.3

§1777.3. Factors Considered in Assessing Fines.

~~In assessing the amount of an administrative fine pursuant to section 1777.2, the committee of the board shall consider any one or more of the relevant circumstances presented by any of the parties to the case including, but not limited to, the following:~~

- ~~(1) Whether the respondent has made a reasonable, good faith attempt to comply with the Confidentiality of Medical Information Act (Civil Code Section 56 et seq.).~~

- ~~(2) The nature and seriousness of the misconduct.~~
- ~~(3) The harm to the patient.~~
- ~~(4) The number of violations.~~
- ~~(5) The persistence of the misconduct.~~
- ~~(6) The length of time over which the misconduct occurred.~~
- ~~(7) The willfulness of the defendant's misconduct.~~
- ~~(8) The defendant's assets, liabilities, and net worth.~~

Authority cited: Section 4005, Business and Professions Code; and Section 56.36, Civil Code. Reference: Section 56.36, Civil Code; and Section 4301, Business and Professions Code.

Repeal Section 1777.4

§1777.4. Compliance With Orders of Abatement.

- ~~(a) If a cited person or entity who has been issued an order of abatement is unable to complete the correction within the time set forth in the citation because of conditions beyond his/her or its control after the exercise of reasonable diligence, the person or entity cited may request an extension of time in which to complete the correction from the board. Such a request shall be in writing and shall be made within the time set forth for abatement.~~
- ~~(b) An order of abatement shall either be personally served or served by certified mail. The time allowed for the abatement of a violation shall begin when the order of abatement is issued.~~
- ~~(c) Failure to abate the violation within the time frame specified in the order of abatement, shall constitute a ground for revocation or suspension of the license, permit, or registration. When an order of abatement is not contested or if the order is appealed and the person or entity cited does not prevail, failure to abate the violation charged within the time specified in the citation shall constitute a violation and failure to comply with the order of abatement.~~
- ~~(d) Failure of a person or entity cited to pay a fine within 30 days of the date of assessment, unless the citation is being appealed, may result in disciplinary action by the board. When a citation is not contested and a fine is not paid, the full amount of the fine shall be added to the fee for renewal of the license and the license shall not be renewed without payment of the renewal fee and fine.~~

Authority cited: Section 4005, Business and Professions Code; and Section 56.36, Civil Code. Reference: Section 56.36, Civil Code; and Sections 125.9 and 4301, Business and Professions Code.

Repeal Section 1777.5

§1777.5. Contested Citations.

~~Any person or entity served with a citation may contest the citation by appealing to the board in writing within 30 days of the issuance of the citation. Appeals under this article shall be conducted in accordance with Section 4300(c) of the Business and Professions Code.~~

Authority cited: Section 4005, Business and Professions Code; and Section 56.36, Civil Code. Reference: Section 56.36, Civil Code; and Section 4301, Business and Professions Code.

Article 9.8. Citation and Fine -- Internet Dispensing Violations

Repeal Section 1778

§1778. Authority to Issue Citations.

- ~~(a) A committee of the board may issue citations containing orders of abatement and fines for dispensing or furnishing, or causing to be dispensed or furnished, dangerous drugs or dangerous devices, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination, or if the person or entity did not act in accordance~~

with Section 1761. For the purposes of this article, “committee of the board” means a committee of board members appointed by the board president to consider investigations of alleged violations.

(b) Each citation shall be in writing and shall describe with particularity the nature and facts of the violation, including a reference to the statute or regulations alleged to have been violated. The citation shall be served upon the licensee personally or by certified mail.

(c) A citation must inform the cited person or entity that if he/she or it desires a hearing to contest the citation and/or fine, that hearing shall be requested by written notice to the board within 30 days of the issuance of the citation. Payment of any fine shall not constitute an admission of the violation charged.

(d) A committee of the board shall meet periodically in both the northern and southern portions of the state for the purpose of reviewing alleged violations, including notices of violation issued by the board inspectors, and issuing citations to licensees of the board. A licensee shall appear, upon request of the board, before a committee of the board. The request to appear shall include a summary of alleged violations to be reviewed at that meeting. Persons or entities may reschedule their appearance before a committee of the board to review an alleged violation once. A committee of the board may issue a citation and impose a fine, and/or an order of abatement in the absence of a person or entity who fails to appear a second time. Citations shall be issued within 60 days of the committee meeting where the determination to issue the citation was made.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4067, Business and Professions Code.

Repeal Section 1778.1

§1778.1. Factors Considered in Assessing Fines.

Fines issued pursuant to this article shall not exceed \$25,000 per violation. In assessing the amount of an administrative fine, the committee of the board shall give due consideration to the following factors:

- (a) The gravity of the violation.
- (b) The good or bad faith of the cited person or entity.
- (c) The history of previous violations.
- (d) Evidence that the violation was or was not willful.
- (e) The extent to which the cited person or entity has cooperated with the board's investigation.
- (f) The extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violation.
- (g) Other matters as may be appropriate.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4067, Business and Professions Code.

Repeal Section 1778.2

§1778.2. Compliance With Orders of Abatement.

(a) If a cited person or entity who has been issued an order of abatement is unable to complete the correction within the time set forth in the citation because of conditions beyond his/her or its control after the exercise of reasonable diligence, the person or entity cited may request an extension of time in which to complete the correction from the board. Such a request shall be in writing and shall be made within the time set forth for abatement.

(b) An order of abatement shall either be personally served or served by certified mail. The time allowed for the abatement of a violation shall begin when the order of abatement is issued.

(c) When an order of abatement is not contested or if the order is appealed and the person or entity cited does not prevail, failure to abate the violation charged within the time specified in the citation shall constitute a violation and failure to comply with the order of abatement. Such failure shall constitute a ground for revocation or suspension of the license, permit, or registration.

(d) Failure of a person or entity cited to pay a fine within 30 days of the date of assessment, unless the citation is being appealed, may result in disciplinary action by the board. When a citation is not contested

~~and a fine is not paid, the full amount of the fine shall be added to the fee for renewal of the license and the license shall not be renewed without payment of the renewal fee and fine.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 125.9 and 4067, Business and Professions Code.

Repeal Section 1778.3

§1778.3. Contested Citations.

~~Any person or entity served with a citation may contest the citation by appealing to the board in writing within 30 days of the issuance of the citation. Appeals under this article shall be conducted in accordance with Section 4300(e) of the Business and Professions Code.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4067, Business and Professions Code.